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Original Article

Validation of the traditional Chinese version of the prolapse quality of life questionnaire (P-QOL) in a Mandarin-speaking Taiwanese population

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ABSTRACT

Objective: To validate the traditional Chinese translated version of the prolapse quality of life questionnaire (P-QOL).

Materials and Methods: The P-QOL questionnaire was translated into traditional Chinese characters and administered to women recruited from gynecologic outpatient clinics of Kaohsiung Chang Gung Memorial Hospital, Kaohsiung, Taiwan. After the test–retest reliability and internal consistency were established in a pilot study, all participants completed the P-QOL questionnaire and were examined in the lithotomy position using the Pelvic Organ Prolapse Quantification System (POP-Q). The construct validity was assessed by comparing symptom scores and quality-of-life domain scores between symptomatic and asymptomatic women.

Results: Of the 244 women recruited, 159 were symptomatic for pelvic organ prolapse, and 85 were asymptomatic. The test–retest reliability confirmed a significant positive monotonic correlation between the total scores of each domain ($n = 30$, Spearman's rho was from 0.411 to 0.888, $p < 0.05$ of all). All items achieved a Cronbach $\alpha > 0.80$ showing good internal consistency. Among the 18 symptom questions, the scores differed significantly between symptomatic and asymptomatic women for 12/18 symptom questions. These 12 questions referred to the prolapse/vaginal symptoms. All the quality of life domains differed significantly ($p < 0.05$) between symptomatic and asymptomatic women except for the domain of sleep/energy ($p = 0.108$).

Conclusion: The traditional Chinese language version of the P-QOL is a reliable instrument for the assessment of symptom severity and impact on quality of life in women with pelvic organ prolapse.

Introduction

Pelvic organ prolapse (POP) is a distressing condition that occurs with the loss of the normal supportive system of the pelvic floor, which results in descent of the pelvic organs into the vaginal canal. The associated risk factors include aging, pregnancy, parity, long-term abdominal straining, and connective tissue disorders.[1–3] Symptoms such as “something coming down into the vagina” and “feeling of a vaginal bulge with or without various urinary symptoms” are frequently described by women with POP, and appear to be worse toward the end of the day [4]. POP is not a life-threating condition, but it has a great impact on quality of life, causing physical, social, psychological, occupational, domestic, and sexual limitations [5–7]. A recent study showed that the lifetime risk of surgery for stress urinary incontinence (SUI) or POP in women is 20.0% by the age of 80 years [8]. Clinical examinations are often not sufficient enough to get the precise information regarding the severity of symptoms or quality-of-life decrease. A patient's embarrassment may also make it difficult for global evaluation.

Validated questionnaires such as the Pelvic Floor Distress Inventory (PFDI) and Pelvic Floor Impact Questionnaire (PFIQ) are used in the United States. They are useful condition-specific quality-of-life instruments for women with disorders of the lower

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urinary tract, gastrointestinal tract, and pelvic organ prolapse, measuring the degree of bother and distress caused by a broad array of pelvic floor symptoms [5]. However, their use is limited due to the large number of items included (46 and 93 items, respectively).

In 2005, Digesu et al [6] developed and validated a simple, reliable, and easily comprehensible questionnaire able to characterize symptom severity to assess the impact on quality of life and to evaluate treatment outcomes of women with uterovaginal prolapse. Compared with other validated questionnaires such as the PFDI and the PFIQ [5], the P-QOL is a short form questionnaire with the advantage of being easy to fill out completely. The P-QOL contains 20 questions representing nine quality-of-life domains covering general health, prolapse impact, physical and social limitations, personal relationships, emotional problems, sleep/energy disturbances, sexual problems, as well as measurements of symptom severity. Additionally, 18 questions regarding urinary, bowel, and prolapse/vaginal symptoms are also separately included [6]. The detailed symptomatic items are listed in Table 3. The P-QOL has 38 questions in total and it has been validated in the English [6], Italian [9], Turkish [10], Japanese [11], German [12], and Persian [13] languages. All of these results suggest that it is effective in identifying women requiring treatment for POP.

The use of validated questionnaires is a necessary clinical and research instrument to identify women with POP needing treatment and to evaluate their surgical outcomes [6,14,15]. In the Chinese language, there is no validated quality-of-life questionnaire that measures the impact of pelvic organ prolapse in women. Modern Chinese typically involves two main forms of writing—-Traditional and Simplified Chinese. Traditional Chinese is used in Taiwan, Hong Kong, Macau, and Malaysia; simplified Chinese is used in mainland China (PRC) and Singapore. The aim of this study was to translate and validate a Traditional Chinese version of the P-QOL for Mandarin-speaking Chinese-writing Taiwanese women.

Materials and methods

Questionnaires and linguistic validations

The original English version of the P-QOL questionnaire [5] was translated into traditional Chinese by two professional Chinese–English translators who were unfamiliar with the P-QOL questionnaire.

Content validity

Afterwards, a common draft of the traditional Chinese version was produced with a list of alternatives for the controversial items and response choices. A second meeting included the two translators and Taiwanese physicians with experience in “health and QOL terminology” to make revisions and produce a second draft. Then, 10 symptomatic women were asked to complete the second draft, and they were interviewed for possible ambiguous questions. The process also involved back-translation performed by another different linguistic expert. After the third meeting, the final traditional Chinese version was completed.

Test–retest reliability

Initially, a pilot study was conducted in order to evaluate the internal consistency and test–retest reliability of the Chinese version. We recruited 30 women to complete the final version at the beginning of their visit in the urogynecology outpatient clinic of Kaohsiung Chang Gung Memorial Hospital, Kaohsiung, Taiwan, before being seen by a physician. Questionnaires were printed in large fonts (minimum 16 points) so that the elderly women could read it easily. A nurse specialist was available to assist women who did not read the questionnaires well. To measure the test–retest reliability of the final version, “2-week test–retest analysis” was conducted. The women were asked to complete the same questionnaire again 2 weeks later in the same clinic.

Construct validity

The construct validity was assessed by measuring levels of missing data, comparing symptom scores between symptomatic and asymptomatic women, and lastly comparing symptoms scores with objective vaginal examination findings related to the stage of vaginal prolapse in the symptomatic group.

After the pilot study and based on the English validation study, 245 patients (160 symptomatic women and 85 asymptomatic women) were enrolled in the study between November 2009 and October 2011. Women were defined as symptomatic from prolapse if they complained of any of the prolapse symptoms and/or they reported a “sensation of dragging” or “a lump or fullness in the vagina”. Asymptomatic women had none of the above symptoms. The study focused on individuals with or without prolapse symptoms. Participants were included if they were at least 18 years old and had sexual experience. They were excluded if they were pregnant or mentally or physically incapable of completing the self-administered questionnaires. All of the women completed the P-QOL questionnaire at their hospital visit. The investigators (K.-H.H. and F.-C.C.), blinded as to the scores of the patients, examined each of the women in the lithotomy position using the Pelvic Organ Prolapse Quantification System (POP-Q). Figure 1 shows the flowchart of the process of this study.

Statistical analyses

The P-QOL scores are expressed as medians and quartiles. For test–retest reliability, Spearman's rho nonparametric correlation coefficient (SCC) was used to measure the strength of a monotonic

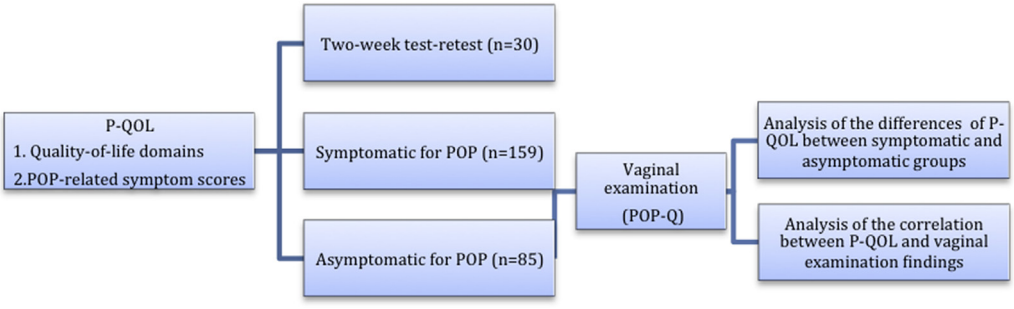

Figure 1. Flowchart of the study process. P-QOL = prolapse quality-of-life questionnaire; POP = pelvic organ prolapse; POP-Q = pelvic organ prolapse quantification.

relationship between paired data and with a subsequent significance testing. The guide for the absolute value of SCC is 0.00–0.19 "very weak", 0.20–0.39 "weak", 0.40–0.59 "moderate", 0.60–0.79 "strong", and 0.80–1.0 "very strong". Spearman's correlation was also used for evaluating the correlation between the vaginal examination findings and the P-QOL scores (divided into prolapse related symptom scores and quality-of-life domain scores) among the symptomatic patients. The P-QOL scores of asymptomatic and the symptomatic participants were compared using Mann–Whitney *U* test and with a power calculation. A p value < 0.05 was accepted as statistically significant. Cronbach α test is a measure of internal consistency to show how closely related a set of items are as a group. A Cronbach α of > 0.7 has been recommended as acceptable.

The Institutional Review Board of Kaohsiung Chang Gung Memorial Hospital approved the study protocol (IRB, 98-3128B).

Results

Of the 245 women included in the study, 160 were symptomatic, and 85 were asymptomatic (controls). Only one questionnaire in the symptomatic group was incorrectly completed and was excluded. Table 1 lists the demographic characteristics of the study population. The mean age was 62 years (range, 35–86) in the symptomatic group and 61 years (range, 33–84) in the asymptomatic group. The body mass index (BMI) and parity were equal in both groups. Of the 159 women in the symptomatic group, 76.7% (122) had Stage III or IV POP based on POP-Q examinations, and 18.9% (30) had Stage II POP. Among the 85 women in the asymptomatic group, 56.5% had Stage 0 POP whereas 43.5% (37) had Stage I or II POP.

In terms of reliability, all items achieved a Cronbach $\alpha > 0.80$ showing good interrater reliability. The test–retest reliability confirmed a significant positive monotonic correlation between the total scores of each domain (Spearman's rho was from 0.411 to 0.888). The subsequent significance testing of all showed $p < 0.05$ (Table 2).

Among the 18 symptom questions in the traditional Chinese version of the P-QOL questionnaires, the scores differed significantly between the symptomatic and asymptomatic women for 12/18 symptom questions (Table 3). These 12 questions referred to urinary symptoms (S1, S2, S3, S9, S10, S11), prolapse/vaginal symptoms (S5, S6, S8, S16), and bowel symptoms (S7, S12). Table 4 shows that only five symptom questions significantly correlate with objective vaginal examination findings in the symptomatic group (S5 = feeling a bulge/lump from or in the vagina; S6 = heaviness or dragging feeling as the day goes on from the vagina or the lower abdomen; S8 = discomfort in the vagina, which is worse when standing and relieved by lying down; S9 = poor urinary stream; and S15 = vaginal bulge which gets in the way of sex).

The scores for the P-QOL domains differed significantly between symptomatic and asymptomatic women for general health perceptions, prolapse impact, role limitations, physical limitations, social limitations, personal relationships, and emotional and severity measures ($p < 0.05$); the domain of sleep/energy was an exception ($p = 0.108$, Table 5). P-QOL domain scores and vaginal examination findings also correlated strongly in most items except for the emotional and sleep/energy domains (Table 6).

Table 1
Demographic study population characteristics.

	Symptomatic	Asymptomatic	*p*
No.	159	85	
Age (y)	62 (35–86)	61 (33–84)	0.538
BMI (kg/m^2)	23 (22–26)	24 (22–26)	0.140
Parity			0.862
0	0 (0)	2 (1.3)	
1	1 (1.2)	4 (2.6)	
2	17 (21.0)	31 (19.9)	
≥3	63 (77.8)	119 (76.3)	
DM	13 (15.3)	24 (15.0)	0.951
HTN	24 (28.2)	61 (38.1)	0.122
Stage			<0.001
0	48 (56.5)	0 (0)	
1	26 (30.6)	7 (4.4)	
2	11 (12.9)	30 (18.9)	
3	0 (0)	96 (60.4)	
4	0 (0)	26 (16.4)	

Data are presented as *n* (%) or mean (interquartile range).
* $p < 0.05$ is considered statistically significant.
BMI = body mass index; DM = diabetes mellitus; HTN = hypertension.

Table 2
Test–retest reliability scores for the Prolapse Quality of Life Questionnaire (P-QOL). Spearman's rho nonparametric correlation coefficient (SCC) between the total scores of each domain ($n = 30$).

Prolapse quality of life domain scores	*SCC*	*p**	R^2 (%)[a]
General health perceptions	0.709	<0.001	50.2
Prolapse impact	0.888	<0.001	78.9
Role limitations	0.411	0.024	16.9
Physical limitations	0.577	0.001	33.3
Social limitations	0.609	<0.001	37.1
Personal relationships	0.699	<0.001	48.8
Emotions	0.518	0.003	26.8
Sleep/energy	0.594	0.001	35.2
Severity measures	0.719	<0.001	51.7

* $p < 0.05$ is considered statistically significant.
[a] The squared correlation coefficient (R^2) is the proportion of variance.

Discussion

We translated the English P-QOL originated by Digesu et al [6] into a traditional Chinese language version and validated it. The traditional Chinese version has a structure similar to the English version, including prolapse related symptom scores (18 items) and quality of life domain scores (7 domains including 20 questions). Our goal is to have a validated, applied questionnaire for evaluation of the prolapse related symptoms and the impact on quality of life for Taiwanese women.

We found that 95.6% of the symptomatic women had Stages II–IV urogenital prolapse, and 12.9% of the asymptomatic women had Stage II urogenital prolapse. This finding concurs with a previous report that most often women become symptomatic once the pelvic organs prolapse onto the hymen, which occurs in some Stage II and all Stages III and IV cases [16].

Previously, investigators reported that increasing severity of POP is weakly associated with specific symptoms related to urinary incontinence and defecation dysfunction [17–19]. This may reflect the fact that the aetiology of lower urinary tract symptoms (LUTS) is multifactorial including anatomical and functional factors. Pelvic organ prolapse may result in kinking or compression of the urethra and cause bladder outlet obstruction (BOO) or mask stress urinary incontinence. Regardless of the etiology, BOO produces resistance upon the bladder outflow channel and results in LUTS, which may be predominantly voiding, storage, or often a combination of both. Overactive bladder (OAB) is characterized by urinary urgency with or without urgency urinary incontinence (UUI) and is usually accompanied by frequency and nocturia. In our study, S1, S2, and S3 stands for frequency, urgency, and UUI, respectively, to evaluate OAB. All of the three items showed significant differences between symptomatic and asymptomatic patients. The incidence of

Table 3
Pelvic organ prolapse-related symptom scores of symptomatic and asymptomatic women.

	Prolapse related symptom scores	Symptomatic	Asymptomatic	p^*
S1	Going to the toilet to pass urine very often	2.14 ± 0.99 2 (1–3)	1.36 ± 0.74 1 (1–1)	<0.001
S2	Urgency: A strong desire to pass urine	1.81 ± 0.94 2 (1–3)	1.26 ± 0.62 1 (1–1)	<0.001
S3	Urge incontinence: Urinary leakage associated with a strong desire to pass urine	1.79 ± 1.00 1 (1–3)	1.28 ± 0.68 1 (1–1)	<0.001
S4	Stress incontinence: Urinary leakage associated with coughing	1.86 ± 0.99 2 (1–2)	1.60 ± 0.76 1 (1–2)	0.070
S5	Feeling a bulge/lump from or in the vagina	2.94 ± 0.93 3 (3–4)	1.05 ± 0.38 1 (1–1)	<0.001
S6	Heaviness or dragging feeling as the d goes on from the vagina or the lower abdomen	2.58 ± 0.98 3 (2–3)	1.07 ± 0.40 1 (1–1)	<0.001
S7	Vaginal bulge interfering with you emptying your bowels	1.68 ± 0.94 1 (1–2)	1.11 ± 0.56 1 (1–1)	<0.001
S8	Discomfort in the vagina that is worse when standing and relieved by lying down	2.38 ± 1.02 3 (1–3)	1.09 ± 0.45 1 (1–1)	<0.001
S9	Poor urinary stream	2.35 ± 1.08 3 (1–3)	1.27 ± 0.59 1 (1–1)	<0.001
S10	Straining to empty your bladder	1.62 ± 0.91 1 (1–2)	1.13 ± 0.40 1 (1–1)	<0.001
S11	Urine dribbles after emptying your bladder	1.99 ± 1.02 2 (1–3)	1.24 ± 0.59 1 (1–1)	<0.001
S12	Bowels do not feel completely empty after opening	1.60 ± 0.88 1 (1–2)	1.27 ± 0.63 1 (1–1)	0.002
S13	Constipation: difficulty emptying bowels	1.38 ± 0.76 1 (1–1)	1.29 ± 0.67 1 (1–1)	0.468
S14	Straining to open your bowels	1.34 ± 0.69 1 (1–1)	1.21 ± 0.64 1 (1–1)	0.148
S15	Vaginal bulge which gets in the way of sex	0.81 ± 1.13 0 (0–1)	0.66 ± 0.72 1 (0–1)	0.674
S16	Lower backache worsens with vaginal discomfort	1.50 ± 0.82 1 (1–2)	1.06 ± 0.36 1 (1–1)	<0.001
S17	Do you help empty your bowels with your fingers	1.06 ± 0.37 1 (1–1)	1.07 ± 0.43 1 (1–1)	0.812
S18	How often do you open your bowels	1.75 ± 0.74 2 (1–2)	1.85 ± 0.70 2 (1–2)	0.260

Data are presented as mean ± standard deviation or median (interquartile range). Calculated with Mann–Whitney *U* test.
* $p < 0.05$ is considered statistically significant.

frequency, urgency, and UUI are 64.8%, 46.5%, and 50.9% in the symptomatic group; 23.6%, 16.5%, and 16.5% in the asymptomatic group. For SUI (S4), with incidence at 54.1% versus 45.9%, showed no significant difference between symptomatic and asymptomatic POP patients. In the six items of bowel symptoms evaluation, S7 (vaginal bulge interfering with you emptying your bowels) and S12 (bowels do not feel completely empty after opening) showed significant differences between symptomatic and asymptomatic patients, with incidence at 42.1% versus 5.9% in S7, and 36.5% versus 18.8% in S12. Symptom (S15) regarding vaginal bulge which gets in

Table 4
Spearman's correlation coefficients (SCC) between prolapse related symptom scores and vaginal examination findings in the symptomatic pelvic organ prolapse group ($n = 159$).

	Prolapse related symptom scores	SCC	*p*
S1	Going to the toilet to pass urine very often	−0.012	0.876
S2	Urgency: A strong desire to pass urine	−0.016	0.843
S3	Urge incontinence: Urinary leakage associated with a strong desire to pass urine	0.078	0.328
S4	Stress incontinence: Urinary leakage associated with coughing	−0.132	0.098
S5	Feeling a bulge/lump from or in the vagina	0.352	<0.001
S6	Heaviness or dragging feeling as the day goes on from the vagina or the lower abdomen	0.289	<0.001
S7	Vaginal bulge interfering with you emptying your bowels	0.014	0.857
S8	Discomfort in the vagina that is worse when standing & relieved by lying down	0.204	0.010
S9	Poor urinary stream	0.221	0.005
S10	Straining to empty your bladder	0.062	0.437
S11	Urine dribbles after emptying your bladder	0.091	0.255
S12	Bowels do not feel completely empty after opening	−0.086	0.281
S13	Constipation: Difficulty emptying bowels	−0.067	0.399
S14	Straining to open your bowels	−0.044	0.581
S15	Vaginal bulge that gets in the way of sex	−0.310	<0.001
S16	Lower backache worsens with vaginal discomfort	0.022	0.785
S17	Do you help empty your bowels with your fingers	−0.025	0.752
S18	How often do you open your bowels	0.049	0.536

* $p < 0.05$ is considered statistically significant.
SCC = Spearman's correlation coefficients.

Table 5
Prolapse quality of life domain scores of symptomatic and asymptomatic women with pelvic organ prolapsed.

Prolapse quality of life domain scores	Symptomatic	Asymptomatic	*p*	Power
General health perceptions	50 (25–50)	25 (25–50)	0.001	0.908
Prolapse impact	67 (33–67)	0 (0–33)	<0.001	1.000
Role limitations	33 (0–67)	0 (0–33)	<0.001	0.999
Physical limitations	50 (17–67)	0 (0–17)	<0.001	1.000
Social limitations	33 (0–67)	0 (0–8)	<0.001	0.999
Personal relationships	25 (17–33)	17 (8–25)	0.001	0.936
Emotions	44 (33–67)	0 (0–22)	<0.001	1.000
Sleep/energy	17 (0–50)	17 (0–33)	0.108	0.528
Severity measures	25 (8–42)	0 (0–8)	<0.001	1.000

Data are presented as median (interquartile ranges). Calculated with Mann–Whitney *U* test and power calculation are shown.
* $p < 0.05$ is considered statistically significant.

the way of sex is not significantly distinguishable between symptomatic and asymptomatic women. The limitation of this item may be due to it not being clear if women are currently sexually active.

In the symptomatic group, we found only five symptom items (S5, S6, S8, S9, and S15) significantly correlated with the vaginal examination findings (severity of prolapse). Symptom scores of feeling a lump from the vagina, heaviness feeling as the day goes on, discomfort in the vagina that is worse when standing and relieved by lying down, poor urinary stream, and vaginal bulge that gets in the way of sex, are the indicators which show the severity of prolapse. In our study, the construct validity testing the correlation between symptom items of P-QOL and severity of prolapse is limiting. The precise evaluation of severity of prolapse needs pelvic examination performed by a specialist.

We found distinguishable differences between symptomatic and asymptomatic women in the quality of life domains, including general health perceptions, prolapse impact, role limitations, physical limitations, social limitations, personal relationships, and emotional and severity measures, but not in the domain of sleep/energy. This analysis also confirmed that all of the items in the quality of life questionnaire correlated significantly with the objective vaginal examination findings of prolapse severity except for those in the emotional and sleep/energy domains. We supposed that lying down was a good position to relieve the sinking pressure feeling of POP, so POP impacted sleep and energy less than when a patient was in an upright position.

A limitation of our study is that we had 30 women for test–retest just as a quote from original P-QOL study design and its other language versions, and the number of subgroup may be too low to make test–retest analysis. Also, another limitation is the lack of other criterion comparators such as PFDI, PISQ, and PFIQ for both P-QOL item and domain values.

The traditional Chinese version of P-QOL proved to be a valid, reliable, and easily comprehensible instrument for assessing symptom severity, impact, and quality of life of Mandarin-speaking Chinese-writing Taiwanese women with pelvic organ prolapse.

In conclusion, the traditional Chinese translation of P-QOL was validated. The questionnaire consists of a symptom inventory and a quality-of-life assessment, and it contains a reasonable number of questions. It is a reliable instrument for the assessment of related symptoms and impact on quality of life in women with pelvic organ prolapse. We suggest the traditional Chinese translation of P-QOL to be a part of global evaluation of pelvic organ prolapse of Mandarin Chinese-speaking women.

Table 6
Spearman's correlation coefficients (SCC) between pelvic organ prolapse quality-of-life domain scores and vaginal examination findings in the symptomatic group ($n = 159$).

Prolapse quality of life domain scores	SCC	*p*
General health perceptions	0.165	0.044
Prolapse impact	0.203	0.013
Role limitations	0.167	0.041
Physical limitations	0.189	0.020
Social limitations	0.166	0.042
Personal relationships	−0.171	0.036
Emotions	0.143	0.081
Sleep/energy	−0.044	0.597
Severity measures	0.309	<0.001

* $p < 0.05$ is considered statistically significant.
SCC = Spearman's correlation coefficients.

Conflicts of interest

The authors have no conflicts of interest relevant to this article.

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